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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,082	05/19/2004	Piera S. Sun	201040/1091	5673

7590 02/14/2006

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/849,082	SUN, PIERA S.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments and amendments filed 11/14/2005 have been entered.

2. Claim 1 has been amended.

3. Claims 11-13 are cancelled.

4. Rejection of claim 1 under 35 USC 101 is withdrawn.

5. Rejection of claims 1-17 under 35 USC 112, first paragraph is withdrawn.

6. Claims 1-17 are examined in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6-7, 9, and 11-13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tseng et al. (2000, Theriogenology, Vol. 54, pgs. 1421-1432) for reasons of record in the office action mailed 08/10/2005.

Claims 1-2, 4, 6-8, 9, and 11-13 are drawn to a method of nucleic acid molecule delivery into a fertilized shrimp egg comprising: providing a fertilized shrimp egg prior to its formation of a protective layer; providing a nucleic acid molecule; and combining the nucleic acid molecule and the fertilized shrimp egg under conditions effective to allow the nucleic acid molecule to be delivered into the egg, wherein the nucleic acid molecule is heterologous to the egg, wherein the nucleic acid molecule is in an expression vector, wherein the expression vector is a circular

vector, wherein the expression vector and nucleic acid molecule comprises a label, wherein the eggs is from a species selected from a group of marine fish, freshwater fish, and crustaceans, and wherein the egg is a shrimp egg.

Response to Arguments

Applicants argue in amendment filed 11/14/2005 that the Tseng et al. reference does not teach all the limitations of claim 1. Specifically the limitation of issue is that Tseng et al. do not teach a method of nucleic acid molecule delivery into a fertilized shrimp egg by first providing a fertilized shrimp egg prior to the formation of a jelly coat. This argument is not persuasive. The instant specification teaches that 12-18 minutes after spawning a new jelly layer begins to form around the egg's exterior, and that in approximately 20-45 minutes after spawning, the jelly layer is fully formed into a hatching membrane (pg. 19 lines 15-29). Tseng et al. teach that shrimp zygotes were collected 30 minutes after spawning and that 366 zygotes in 100 ul of solution and 10141 zygotes in 1 ml of solution were electroporated (Tseng et al., pg. 1423 parag. 2). Since these shrimp zygotes were collected at 30 minutes after spawning the jelly coat would not be formed, only in the process of forming. Further Tseng et al. removed the jelly coat 30 minutes after spawning only to permit the successful electroporation of DNA, which was a preventative measure explained in the last sentence of paragraph 3 on page 1422, again the jelly coat is only forming and is not complete. Thus Tseng et al. clearly anticipate the invention of claims 1-2, 4, 6-7, 9, and 11-13, and for reasons of record and above the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 10, and 14-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tseng et al. (2000, Theriogenology, Vol. 54, pgs. 1421-1432), in view of Godbey et al. (1999, J. of Controlled Release, Vol. 60, pgs. 149-160) for reasons of record in the office action mailed 08/10/2005.

Claims 1, 3, 5, 10, and 14-17 are drawn to a method of nucleic acid molecule delivery into a fertilized egg comprising using a nucleic acid molecule that is homologous to said egg, wherein said expression vector is a linear vector, wherein said nucleic acid is a label selected from a the group consisting of a radio-active label, a fluorescent label, a chemiluminescent label, and a biotinylated label, the use of a transfection reagent with the nucleic acid molecule and the fertilized egg, wherein said transfection reagent is selected from the group consisting of a cationic lipid reagent, a liposomal cationic lipid reagent, a cationic non-liposomal lipid reagent, an activated dendrimer reagent, and a cationic polyethyleneimine reagent, wherein the transfection reagent is a cationic polyethyleneimine, and wherein the transfection reagent is a linear cationic polyethyleneimine reagent.

Response to Arguments

Applicants argue in amendment filed 11/14/2005 that the Godbey et al. reference does not teach or suggest a method of nucleic acid molecule delivery into a fertilized shrimp egg. Further the applicant argues that Gobey et al. in combination with Tseng et al. does not teach all the limitations of the claim, specifically as discussed in the 102(b) rejection above, using a fertilized shrimp egg prior to the formation of a protective layer. Applicant continues to argue that Godbey states that "increasing transfection efficiency while reducing toxicity must be accomplished before PEI can ultimately be used for efficacious gene therapies", and that one skilled in the art would not be motivated to combine the PEI transfection method taught by Godbey with the method of Tseng. These arguments are not persuasive. With regard to Godbey stating the limitations of PEI in gene therapy, the instant claims are not drawn to gene therapy, but the creation of transgenic shrimp, two entirely different fields of molecular biology, and thus do not argue the merits of the rejected claims. Godbey does teach that PEI is used successfully for the transfection of nucleic acid both in vitro and in vivo into cell systems, and there is nothing in the Godbey reference that would suggest that PEI would not successfully work in the production of transgenic shrimp. Godbey states that PEI transfection does work successfully and with excellent transfection efficiency under controlled conditions. This is sufficient motivation to use PEI in the production of transgenic shrimp. As discussed above Tseng et al. do teach all the limitations of the rejected claims, and thus in combination with Godbey would motivate and teach the ordinary artisan to make and use the claimed invention of claims 1, 3, 5, 10, and 14-17. Thus for reasons of record and above the rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, PhD

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER